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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,989	12/28/2001	Ronald J. Pettis	7767-177409	4392

7590 02/24/2005

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EXAMINER
WILLIAMS, CATHERINE SERKE

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,989	PETTIS ET AL.	
	Examiner	Art Unit	
	Catherine S. Williams	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *69-75,77-95 and 97-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *69-75,77-95 and 97-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/23/02;1/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 10/23/2002 lists a foreign reference number different from the reference submitted for document #BH. The document submitted has a reference number of 99/64850 whereas the # listed on the IDS is 99/64580.

Additionally, not all of the references listed on the IDS filed 1/18/05 have been located in the parent applications. The paper files for application #s 09/835,243 and 09/417,671 have been ordered in an attempt to locate the remainder of the documents. These applications have not yet been received; however, these references will be initialed on the IDS when the parent applications are received. In the chance that the references are no longer part of the parent applications, applicant may submit the missing references in order to speed prosecution.

Claim Objections

Claim 69 is objected to because of the following informalities: "the dosage" in line 6 should be recited as –a dosage--. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 69-72,74-75,77-89,94-95 and 97-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (US Pat# 5,527,288) in view of Srivastava (USPN 6,007,821). Gross discloses an intradermal compartment drug delivery device that includes administering a substance through a small gauge hollow needle. As shown in figure 3, the diameter of the outlet opening is about 1/3 the length of the needle. Therefore, if the length of the needle is between 0.3 to 3.0 mm then the outlet opening is about 0.1-1.0 mm. The needle has an outlet at a depth of between most preferably .3 to 1.0 mm when inserted into the dermis which as disclosed would result in delivery of the substance at a depth of between .3 to 2 mm. See 2:18-21. Additionally, Gross discloses that "the drug is delivered directly to a capillary-containing tissue and has no barriers to pass through before entering the vascular system". See 3:50-52. This capillary-containing tissue is the intradermal compartment even though that term is not used in Gross' specification. The diameter of the needle is 0.1-0.2mm. The substances for injection include a variety of substances that include peptides, proteins, hormones, insulin, nucleic acids, and hydrophobic and hydrophilic compositions. See 6:59+. As shown in figure 3, the needle is inserted perpendicularly into the skin. Means for actively discharging the drug include an infusion pump. See 2:31-35. Example 1 and 2 disclose an infusion flow rate of 0.1 ml/min. See 10:60+.

Gross meets the claim limitations as described above but fails to include that the dosage of the substance for achieving a biological effect is reduced by at least 10%-30% compared to when the substance is delivered to a subcutaneous compartment. However, Srivastava discloses a method for treatment of autoimmune disease that includes the teaching that "while both subcutaneous and intradermal routes of administration are effective, intradermal injections

typically require a lower dosage and are, therefore, preferred with respect to economy of materials". See 20:3-6. As demonstrated in the example in section 6 the effective dose is 100 μg subcutaneously and 10 μg intradermally, i.e. 10% less. See 20:7-10. Additionally, one can look at the teaching of Srivastava and "a biological effect" can be considered to be the mere uptake of the substance by the intradermal compartment into the blood stream. Using the intradermal compartment uptake as the biological effect, one can reduce (as taught by Srivastava) the dosage of the substance by at least 30% or more to achieve this uptake (biological effect) which would not be achieved at all through subcutaneous administration regardless of the amount of the dosage.

At the time of the invention, it would have been obvious to use the invention of Gross to administer the composition at the reduced intradermal dosage value (from 10 to 30 percent) as taught by Srivastava. Both device are analogous in the art of intradermal drug delivery; therefore, a combination is proper. Additionally, Srivastava teaches that intradermal injection is a preferred route of delivery for the gp96 protein and Gross teaches that typical drugs for delivery include proteins. One skilled in the art would recognize that the motivation for the combination would be to use the device of Gross for its intended use.

Claims 69,73,77-78,85,93 and 97-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (US Pat# 5,800,420) in view of Srivastava (USPN 6,007,821). Gross discloses an intradermal compartment drug delivery device that includes administering a substance through a small gauge hollow needle having an outlet with an exposed height of between most preferably .3 to 1.0 mm which as disclosed would result in delivery of the

substance at a depth of between .3 to 2 mm. See 10:32-39. The disclosure also indicates that the device can be used to deliver a bolus injection (applicant's disclosure defines a bolus as an amount delivered in less than 10 minutes, see Summary paragraph 22). See 3:29-32. Additionally, Gross discloses that "communication can be established with the capillary system of the dermis". See Paragraph 4 of the Detailed Description of the Invention. This capillary-containing tissue is the intradermal compartment even though that term is not used in Gross' specification.

Gross meets the claim limitations as described above but fails to include that the dosage of the substance for achieving a biological effect is reduced by at least 10%-30% compared to when the substance is delivered to a subcutaneous compartment. However, Srivastava discloses a method for treatment of autoimmune disease that includes the teaching that "while both subcutaneous and intradermal routes of administration are effective, intradermal injections typically require a lower dosage and are, therefore, preferred with respect to economy of materials". See 20:3-6. As demonstrated in the example in section 6 the effective dose is 100 μg subcutaneously and 10 μg intradermally, i.e. 10% less. See 20:7-10. Additionally, one can look at the teaching of Srivastava and "a biological effect" can be considered to be the mere uptake of the substance by the intradermal compartment into the blood stream. Using the intradermal compartment uptake as the biological effect, one can reduce (as taught by Srivastava) the dosage of the substance by at least 30% or more to achieve this uptake (biological effect) which would not be achieved at all through subcutaneous administration regardless of the amount of the dosage.

At the time of the invention, it would have been obvious to use the invention of Gross to administer the composition at the reduced intradermal dosage value (from 10 to 30 percent) as taught by Srivastava. Both device are analogous in the art of intradermal drug delivery; therefore, a combination is proper. Additionally, Srivastava teaches that intradermal injection is a preferred route of delivery for the gp96 protein and Gross teaches that typical drugs for delivery include proteins. One skilled in the art would recognize that the motivation for the combination would be to use the device of Gross for its intended use.

Claims 90-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Gross in view of Srivastava in further view of Palmer (US Pat# 6,537,242). Both Gross references in view of Srivastava independently meet the claim limitations as described above for claim 85 but both fail to teach an array of microneedles that includes at least 6 needles.

However, Palmer discloses an intradermal drug delivery device that includes an array of microneedles that includes at least 6 needles. See figure 5. The device of Palmer is designed as an "apparatus for enhancing the penetration of a penetrating device into the skin of a patient". See Summary of Palmer. It is noted that these claims have been given a priority date back to 6/29/2001.

At the time of the invention it would have been obvious to incorporate the teaching of a needle array of Palmer into the invention of Gross in view of Srivastava. All the references and the instant invention are analogous in the art; therefore, a combination is proper. Additionally, the motivation for the incorporation is provided by Palmer in that the incorporation of the needle array would enable "enhancing the penetration". See Palmer.

Double Patenting

The nonstatutory double patenting rejection in the previous office action has been withdrawn in light of the amendment dated 1/18/05.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine S. Williams
Catherine S. Williams
February 21, 2005